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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,814	06/13/2001	Andrea Buchacher	P66014US1	4216

7590

02/19/2003

LAW OFFICES OF
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EXAMINER

MAYES, LAURIE A

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 02/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,814

Applicant(s)

BUCHACHER ET AL.

Examiner

Laurie Mayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The applicant's response received January 2, 2003 has been entered. Claims 14-26 have been cancelled and new claims 27-37 added. Claims 27-37 are pending and examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27 is indefinite because it is unclear whether or not "... a mixture containing virus-inactivated plasma proteins ..." means:

- (a) the proteins have been inactivated by a virus; or,
- (b) treated to inactivate viral particles in the mixture.

The language in the claim does not appear to clearly set forth: "... a mixture containing plasma proteins in activated virus ...".

Claim 27 would also be clearer when "... -fractions exiting at ... design are collected" is changed to "... -fractions comprising the separated proteins exiting ... are collected". This would result in the process steps being commensurate to the preamble of the claim. In addition, please consider (in line 3 of the claim) changing "... -said mixture ..." to: "... blood plasma or said mixture ...". Claims 28-37 are included since they do not eliminate the above issues.

The argument presented (paper #8, pp. 3-4) regarding the 112 second paragraph rejection is noted but unpersuasive for the reasons indicated in the stated rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Antanavich et al. (United States Patent Number 5,585,007) in view of Holm (United States Patent Number 5,733,446). Antanavich et al. teach a method for the separation of blood plasma (col. 1, lines 12-14) wherein the blood and/or a thrombin eluent (col. 15, lines 22-25) is/ are applied to a separation medium having an annular design (Fig. 3; col. 11, lines 12-18), being made of polymeric block material (e.g., col. 14, lines 17+) and having a layer of application medium of spherical particles (col. 13, lines 20-21) with a hydrophobic surface applied thereon, namely, hydrophobic foam (col. 13, line 23), where the design of the media is used for chromatography based on hydrophobic interactions or molecular size exclusion (col. 14, lines 17-36) and said separation medium is rotated essentially vertically about an axis which is defined in the direction of flow of the mixture through the separation medium having the annular design (col. 13, lines 25-38), where an eluent is passed through the separation medium having the annular design, where fractions exit an outlet of the separation medium (col. 15, lines 47-58, inlet and outlet) and wherein said separation medium due to its annular design is continuously regenerated by the introduction of new plasma, simultaneous with the separation of the plasma proteins (Fig. 6). Thus Antanavich et al. does teach the separation of blood plasma (col. 10, lines 44+) containing

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a variety of proteins but does not explicitly teach separation of one protein from another per se; the Holm reference teaches a method of isolating proteins such as thrombin and fibronectin from blood plasma or other plasma proteins (col. 7, lines 19-27) comprised of applying a plasma mixture containing said proteins into a separation medium having an annular design (claim 1, col. 16, line 38) and which is rotated essentially vertically about an axis which is defined in the direction of flow of the mixture through the separation medium having the annular design (Figs. 1 and 2), where an eluent is passed through the separation medium and where the resulting fractions are collected (col. 15, lines 38-40 and col. 16, lines 10-12), where said mixing, separating and fractioning are performed continuously (claim 29). While Holm does teach the use of an application medium of an enzyme applied to the separation medium (col. 12, lines 1-5), Holm does not teach the use of spherical particles with a hydrophobic surface applied thereon as an application medium. Given that Antanavich et al. teach the advantages of using spherical particles with a hydrophobic surface as an application medium for use in an annular centrifugal separation device for the purpose of isolating blood plasma and that Holm teaches the advantage of isolating proteins from blood plasma using a similar annular, centrifuge separation medium, it would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to use spherical particles with a hydrophobic surface as an application medium in an annular, centrifuge separation medium for the purpose of isolating any of the proteins in blood plasma from each other.

The comments in applicant's response (filed on January 2, 2003) at pages 4-7 have been considered but are unpersuasive in view of the above stated rejection for obviousness.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 7 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 305-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

L. Mayes

Laurie Mayes
Patent Examiner
Art Unit 1653
February 13, 2003

Christopher S. F. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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